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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,049	06/21/2006	Ahmed Sheriff	P71162US0	5348

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
12/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,049	SHERIFF ET AL.	
	Examiner	Art Unit	
	Lorraine Spector	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-56* is/are pending in the application.

4a) Of the above claim(s) *52-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *30-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I in the reply filed on 8/26/08 is acknowledged. Claims 30-51 are under consideration. It is noted that Invention III was redundant, and is removed, as it is encompassed by Inventions I and II.

Claims 30-35, 40-41, 49-51 link(s) inventions I and II. The restriction requirement pertaining to the linked inventions is **subject to** the nonallowance of the linking claim(s), as enumerated above. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Objections

The claims are objected to for encompassing non-elected inventions. Correction is required.

Claims 32-33 recite limitations directed to intended use, which do not affect the structure of the claimed antibody. Therefore, these claims fail to further limit the claim from which they depend, And are improper dependent claims.

Claim Interpretation

Because the limitations of claims 32-33 fail to further limit, those limitations will not be given weight in applying the prior art. Siilarly, the disease recited in claim 50 are merely intended use, and not given weight in applying the prior art, other than the composition *could* be used suchly, even if the prior art did not appreciate such.

The recitation "recombinant", without any limitation as to host cell, is a product by process limitation that does not affect the nature of the product. Accordingly, such is not given weight in consideration of claims 37 or 49.

Claim Rejections - 35 USC § 112

Claims 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 recites "a nucleic acid" comprising (multiple) "nucleotide sequences" encoding the compound of claim 30. As there is no specific compound of claim 30, and as it is not clear how many nucleotide sequences may be present, the metes and bounds of the claim cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30-34, and 49-51 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,838,433 (Serlupi-Crescenzi et al.).

Serlupi-Crescenzi et al teach IL-6 antagonist peptides (title). The claims encompass the peptides and pharmaceutical compositions thereof. As the recitation of "recombinant" in claim 49 does not affect the structure of the peptide, it is given not weight. Accordingly, the claims are anticipated.

Claims 30-50 are rejected under 35 U.S.C. 102(e) as being anticipated by WO02/34292 published 5/2/02, filed in the US under rule 371 which matured to patent U.S. Patent No.7,320,792 (Ito et al.). Since the publication was in Japanese, the US patent will be referred to for the teachings therein.

Ito discloses anti-human IL-6 antibodies, and teaches administration of humanized anti-IL-6 antibodies, see claim 3. Cols. 2-3 teach anti-IL-6 Ab, including polyclonal and monoclonal (col. 3 lines 4-5). Recombinant expression of antibodies is taught at col. 3, lines 9-15. Chimeric and humanized antibodies are disclosed at columns 7-8. Non-human eukaryotic host cells are disclosed at the bottom of column 9. Fragments including scFV are disclosed at the bottom of column 10.

Accordingly, the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. as applied to claims 30-50 above, and further in view of U.S. Patent No. 7344716 (Di Mauro et al.)

Claim 51 introduces the additional limitation that the medicament contain a CRP antagonist or binding molecule, anti-IL-1-beta molecule, PLA2 antagonists or blockers, and/or complement blockers.

Ito does not teach these specific additional ingredients. DiMauro et al. teach transdermal administration of cytokine inhibitors to treat degenerative disk disease, including those for IL-C and PLA2; see column 5 beginning at line 26. Accordingly, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to include both an anti-IL-6 antibody with a CRP inhibitor (antagonist) in said composition with a reasonable expectation of achieving a result at least as good as with either alone. Accordingly, the invention is *prima facie* obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday from 9-5, and Tuesday, Thursday and Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Dr. Manjunath Rao, at telephone number 571-272-0939.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lorraine Spector/
Primary Examiner
Art Unit 1647